Food and Drug Administration, HHS

- (a) *Identity*. For the purpose of this section, the polyetherimide resin is 1,3-isobenzofurandione, 5,5'[(1-methylethylidene)bis(4,1-phenyleneoxy)] bispolymer with 1,3-benzenediamine (CAS Reg. No. 61128–46–9), and is derived from the condensation reaction of *m*-phenylenediamine and bisphenol Adianhydride.
- (b) Optional adjuvants. The basic polymer identified in paragraph (a) of this section may contain optional adjuvant substances required in the production of basic resins or finished foodcontact articles. The optional adjuvant substances required in the production of the basic polymer may include substances permitted for such use by applicable regulations as set forth in part 174 of this chapter.
- (c) Specifications and extractives limitations—(1) Specifications. Polyetherimide resin identified in paragraph (a) of this section shall have an intrinsic viscosity in chloroform at 25 °C (77 °F) of not less than 0.35 deciliter per gram as determined by a method titled "In-Viscosity trinsic of Polyetherimide Using Chloroform as the Solvent," which is incorporated by reference. Copies are available from the Center for Food Safety and Applied Nutrition (HFS-200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or available for inspection at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC
- (2) Extractive limitations. Extractive limitations are applicable to the basic polyetherimide resin in the form of molded discs of thickness 0.16 centimeter (0.063 inch). The resin discs when extracted with distilled water at 121 °C (250 °F) for 2 hours yield total nonvolatile extractives of not more than 12.3 micrograms per square centimeter.

[50 FR 31351, Aug. 2, 1985; 50 FR 35535, Sept. 3, 1985]

§ 177.1600 Polyethylene resins, carboxyl modified.

Carboxyl-modified polyethylene resins may be safely used as the food-contact surface of articles intended for use in contact with food in accordance with the following prescribed conditions:

(a) For the purpose of this section, carboxyl-modified polyethylene resins consist of basic polymers produced when ethylene-methyl acrylate basic copolymers, containing no more than 25 weight percent of polymer units derived from methyl acrylate, are made to react in an aqueous medium with one or more of the following substances:

Ammonium hydroxide. Calcium carbonate. Potassium hydroxide. Sodium hydroxide.

- (b) The finished food-contact article, when extracted with the solvent or solvents characterizing the type of food and under the conditions of time and temperature characterizing the conditions of its intended use as determined from tables 1 and 2 of §176.170(c) of this chapter, yields total extractives in each extracting solvent not to exceed 0.5 milligram per square inch of foodcontact surface as determined by the methods described in §176.170(d) of this chapter; and if the finished food-contact article is itself the subject of a regulation in parts 174, 175, 176, 177, 178, and §179.45 of this chapter, it shall also comply with any specifications and limitations prescribed for it by that regulation. In testing the finished foodcontact articles, a separate test sample is to be used for each required extracting solvent.
- (c) The provisions of paragraph (b) of this section are not applicable to carboxyl-modified polyethylene resins used in food-packaging adhesives complying with §175.105 of this chapter.

§177.1610 Polyethylene, chlorinated.

Chlorinated polyethylene identified in this section may be safely used as articles or components of articles that contact food, except for articles used for packing or holding food during cooking, subject to the provisions of this section.

(a) For the purpose of this section, chlorinated polyethylene consists of basic polymers produced by the direct chlorination of polyethylene conforming to the density, maximum *n*-hexane extractable fraction, and maximum xylene soluble fraction specifications prescribed under item 2.1 of the table in §177.1520(c). Such chlorinated